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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,862	09/24/2003	Michael T. Barrett	10021287-1	5754

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AGILENT TECHNOLOGIES INC.
INTELLECTUAL PROPERTY ADMINISTRATION, M/S DU404
P.O. BOX 7599
LOVELAND, CO 80537-0599

EXAMINER	
SALMON, KATHERINE D	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/670,862	BARRETT ET AL.	
	Examiner	Art Unit	
	Katherine Salmon	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *22-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21 and 35-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/24/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group 1, Claims 1-21 and 35-40, in the reply filed on 7/17/2006 is acknowledged.

2. Claims 22-34 are withdrawn from consideration.

3. An action on the merits for Claims 1-21 and 35-40 is presented below.

Claim Objections

4. Claims 37-39 are objected to because of the following informalities: Claim 37 needs to be amended to include the limitations of Claim 34 because Claim 34 is withdrawn. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-2 are rejected under 35 U.S.C. 101 because the claimed invention is directed to on-statutory subject matter. The claims are drawn to method of identifying a source of a genomic nucleic acid sample. The methods as claimed, do not produce any physical transformation or produce a tangible result. The claims as written, encompass mere mental steps i.e. identifying a source. The step of identifying a source evaluates a

SNP profile of a sample. This step does not produce any physical transformation or produce a tangible result. The methods merely identify, select or choose SNP profiles for future use, but the future use is not result of the methods as claimed.

It is noted that Claim 4 is drawn to an additional step of future use i.e. screening for the presence of at least one analyte. Further Claim 10 is drawn to additional steps in which the method further comprises assaying sample for the presence of at least one analyte. This suggests the step of "determining the SNP profile" is not an assay. Therefore, Claim 10, in contrast to Claims 1-3 produces a physical transformation and is therefore deemed statutory.

The courts have stated that "While a scientific truth, or the mathematical expression of it, is not patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be."; Warmerdam, 33 F.3d at 1360, 31 USPQ2d at 1759 ("steps of locating' a medial axis, and creating' a bubble hierarchy . . . describe nothing more than the manipulation of basic mathematical constructs, the paradigmatic abstract idea'") (see MPEM § 2106 IV).

The courts have stated that manipulation of abstract concepts or ideas constitute non-statutory subject matter.

> If the "acts" of a claimed process manipulate only numbers, abstract concepts or ideas, or signals representing any of the foregoing, the acts are not being applied to appropriate subject matter. Schrader, 22 F.3d at 294-95, 30 USPQ2d at 1458-59. Thus, a process consisting solely of mathematical operations, i.e., converting one set of numbers into another set of numbers, does not manipulate appropriate subject matter and thus cannot constitute a statutory process.

In practical terms, claims define nonstatutory processes if they:

– consist solely of mathematical operations without some claimed practical application

(i.e., executing a "mathematical algorithm"); or

– **simply manipulate abstract ideas**, e.g. a bid (Schrader, 22 F.3d at 293-94,30

USPQ2d at 1458-59) or a bubble hierarchy (Warmerdam, 33 F.3d at 1360, 31

USPQ2d at 1759), without some claimed practical application.

(see MPEP § 2106 IV (B) (1)).

It is further noted that In re Schrader states: "the grouping or regrouping of bids cannot constitute a physical change, effect or result".... "The only physical effect or result which is required by the claim is the entering of bids in a "record," a step that can be accomplished simply by writing the bids on a piece of paper or chalkboard. For purposes of Section 101, such activity is indistinguishable from the data gathering steps which we said in *In re Grams*, 888 F.2d 835, 12 USPQ 2d 1924 (Fed. Cir. 1989), were insufficient to impart patentability to a claimed involving the solving of a mathematical algorithm". Therefore, the courts have stated that identifying without physical manipulation, is indistinguishable from data gathering and insufficient to impart patentability. Hence, the instant claims drawn to identifying and selecting without any physical manipulation is non-statutory subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 11-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11-21 are unclear. In Claim 11, it is unclear how to determine a SNP profile for said sample to identify said subject. It is unclear the steps involved in determining a SNP profile.

Claim 20 recites the limitation "said condition" in line 2. There is insufficient antecedent basis for this limitation in the claim. It is suggested in order to correct antecedent basis that e.g. the claim depends from Claim 17.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 3-21, and 35-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Hogan et al. (US Patent Application 09/976423 August 15, 2002).

With regard to Claim 1, Hogan et al. teaches a method of providing a sample from a perioperative subject and generating a genomic profile (p. 1 paragraph 12). Hogan et al. teaches identifying the sample on the basis of the profile to determine the course of action during and after surgery (p. 2 paragraph 15). Hogan et al. teaches a genomic profile refers to a set of information such as the presence or absence of a specific set of SNPs (p. 9 paragraph 102). Hogan et al. teaches the profile includes unique genomic identifier (non coding SNPs) to provide a secure accurate internal reference for archiving and tracking genetic data specific to the particular subject (p. 12 paragraph 134). Therefore, the internal reference of the non-coding SNPs placed on the genomic profile is used to identify the source (i.e. identify the subject of the profile).

With regard to Claim 3, Hogan et al. teaches that sample can be from human blood or cultures, which would be considered clinical samples (p. 10 paragraph 111).

With regard to Claim 4, Hogan et al. teaches screening the sample for analytes of clinical relevance such as screened for abnormal B1 adrenergic receptor response (p. 12 paragraph 129).

With regard to Claim 5, Hogan et al. teaches that the profile can be made during the perioperative period wherein the sample would be screened for the presence of the perioperative factors (p. 14 paragraph 150). With regard to Claims 6-7, Hogan et al. teaches the profile can be generated from the subject at the time of birth to be store and later screened when the subject is planning surgery (p. 16 paragraph 186).

With regard to Claim 8, test samples are analyzed for the presence of target DNA molecules using a DNA chip (p. 15 paragraph 173). With regard to Claim 9, Hogan et al. teaches the profile can be generated using a DNA chip hybridization assay (p. 5 paragraph 168).

Claim 10 is drawn to a method comprising assaying a sample for an analyte if the identified SNP profile matches a predetermined source. With regard to Claim 10, Hogan et al. teaches that the SNP profile is tailored to include markers for specific surgical procedures (p. 12 paragraph 132). Therefore a patient is assayed for the presence of particular analytes if the SNP profile matches a patient (source), which is planning a specific surgery such as cardiac or brain surgery (p. 10 paragraph 113).

With regard to Claim 11, Hogan et al. screens a sample (perioperative subject) for at least one analyte (marker for defects for surgery) and determines a SNP profile (generates a genomic profile of patient). (p. 1 paragraph 12, p. 2 paragraph 15, p. 3 paragraph 34 and p. 9 paragraph 102). Hogan et al. teaches a method of providing a sample from a perioperative subject and generating a genomic profile (determining a SNP profile) (p. 1 paragraph 12). Hogan et al. teaches identifying the sample on the basis of the profile to determine the course of action during and after surgery (screening for analytes) (p. 2 paragraph 15). Hogan et al. teaches screening the sample for analytes for surgery, such as, markers for defects in metabolism, malignant hyperthermia, and sepsis (analytes) (p. 3 paragraph 34). Hogan et al. teaches a genomic profile refers to a set of information such as the presence or absence of a specific set of SNPs (p. 9 paragraph 102).

With regard to Claim 12, test samples are analyzed for the presence of target DNA molecules using a DNA chip (p. 15 paragraph 173).

With regard to Claims 13-14, Hogan et al. teaches the profile can be generated from the subject at the time of birth to be store and later screened when the subject is planning surgery (p. 16 paragraph 186). With regard to Claim 15, Hogan et al. teaches that the profile can be made during the perioperative period wherein the sample would be screened for the presence of the perioperative factors (p. 14 paragraph 150).

With regard to Claim 16, Hogan et al. teaches the profile can be generated using a DNA chip hybridization assay (p. 5 paragraph 168).

With regard to Claim 17, Hogan et al. teaches a method of genomic screening to determine if a subject is suitable for medical or surgical treatment (evaluating a subject for a condition) (Abstract). With regard to Claim 18, Hogan et al. teaches a method of screening for co-existing diseases (p. 2 paragraph 13).

With regard to Claim 19, Hogan et al. teaches a method of genomic profile comprising a presymptomatic diagnosis (p. 2 paragraph 13).

With regard to Claim 20, Hogan et al. teaches s method of screening a genomic profile for genetic markers to determine an operative course of action (p. 1 and 2 paragraph 12). Hogan et al. teaches that some markers are related to certain conditions such as defects in metabolism, malignant hyperthermia, and sepsis (p. 3 paragraph 34). Hogan et al., therefore, teaches screening a patient for conditions and therefore monitors a subject.

With regard to Claim 21, Hogan et al. teaches a method in which the sample (subject) is human (p. 10 paragraph 111).

With regard to Claims 35-36, Hogan et al. teaches an array based screening method of determining the condition of a patient for surgery (Abstract). Hogan et al. teaches the profile includes unique gnomic identifier (non coding SNPs) to provide a secure accurate internal referent for archiving and tracking genetic data specific to the particular subject (p. 12 paragraph 134).

With regard to Claim 37, Hogan et al. teaches a method of using an array, which contains SNPs both as identifier of the subject and as markers for disease and conditions associated with surgery (p. 1 and 2 paragraph 12, p. 3 paragraph 34, p. 15 paragraph 173, and p. 12 paragraph 134). Hogan et al. teaches a method of determining a SNP profile based on the pattern of hybridization, which is detected on the array (detecting binding complexes on surface of the array) (p. 15 paragraph 170).

With regard to Claim 38, Hogan et al. teaches a method of taking a sample to a genomic profiling lab and generating raw data (first location), then producing the genomic profile suitable for interpretation by a treating clinician and sending it to the clinician (second location) (p. 17 paragraph 189 and 190). With regard to Claim 39, Hogan et al. teaches the second location can be away from the lab facility and that the data can be provided electronically to the clinician (p. 17 paragraph 192). Therefore the second location is remote from the first location. With regard to Claim 40, Hogan et al. teaches preparing the raw sequence data into a form suitable for interpretation by a

treating clinician such as a report that be printed or displayed on a computer monitor (p. 17 paragraph 190).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan et al. (US Patent Application 09/976423 August 15, 2002) in view of Hunter et al. (US Patent Application 09/822635 November 8, 2001).

Hogan et al. teaches a method of providing a sample from a perioperative subject and generating a genomic profile (p. 1 paragraph 12). Hogan et al. teaches identifying the sample on the basis of the profile to determine the course of action during and after surgery (p. 2 paragraph 15). Hogan et al. teaches screening the sample for analytes for surgery, such as, markers for defects in metabolism, malignant hyperthermia, and sepsis (p. 3 paragraph 34). Hogan et al. teaches a genomic profile refers to a set of information such as the presence or absence of a specific set of SNPs (p. 9 paragraph 102).

Hogan et al., however, does not teach comparing the SNP profile to a reference profile.

Hunter et al. teaches a method of evaluating a subject by comparing the subject expression profile to one or more reference profiles (p. 29 paragraph 357).

Therefore it would have been prime facie obvious to one of ordinary skill in the art to modify the method of Hogan et al. to include a method step of comparing the SNP profile to a SNP reference profile as taught by Hunter et al. The ordinary artisan would be motivated to modify the method of Hogan et al. to include a method step of comparing the SNP profile to a SNP reference profile as taught by Hunter et al., because Hunter et al. teaches a method of using reference profiles to evaluate a subject to determine if the subject is similar a normal target (p 25-26 paragraph 300). The ordinary artisan would be motivated to compare the SNP profile of a patient as taught by Hogan et al. to a control reference sample in order to determine if the patient had the

mutational or wild type marker for specific diseases and conditions associated with surgery progression.

Conclusion

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Salmon whose telephone number is (571) 272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Salmon
Examiner
Art Unit 1634

BJ FORMAN, PH.D.
PRIMARY EXAMINER